ACCE News

Newsletter of the American College of Clinical Engineering

January / February 2010 Volume 20, Issue 1

Check out all the activities that ACCE is planning for HIMSS!

on page 6

In this Issue:

President's Message

Welcome to 2010, a new year sure to be full of clinical engineering activities. The articles included in this newsletter show the promise for a very active society this year.

First , I want to bring your attention to the links on our website of various Haitian earthquake relief options. While ACCE is not directly organizing relief programs, we felt it was important to pass along resources so that members like you can read and decide which effort best matches your capacity to help.

I want you to please read about the many, many activities that ACCE sponsors and consider renewing your membership today. ACCE is a small, grass-roots type organization that needs the support of its members in order to continue. As you will see in ACCE Treasurer Julio Huerta's 2009 financial summary, we had a relatively good year in 2009, but we need 2010 to be better in order to keep up with everything that is going on at the national and international level. So please renew online now through our website: www.accenet.org.

Also, ACCE is once again conducting a membership survey. As we start out the year, we want to know what activities and objectives are important to you. Let us know what education programs or collaborations you would like to see us create. And if you want to get more involved with the organization, you can indicate so and send us your contact information through the survey. Find the survey here at http://www.accenet.org/membersurvey2010/

HIMSS 2010 is just around the corner (HIMSS 2010 in Atlanta, GA from Feb 27-Mar4). This conference continues to grow in importance for clinical engineers as an opportunity to advocate for our profession, as described in this newsletter by Jon Blasingame, as well as a great opportunity to learn about the progress in medical device interoperability (see the article by Manny Furst about IHE PCD demonstrations at HIMSS 2010). These are only 2 of the many activities that we will be engaged in during the formal part of the conference. For more information, please see the ACCE@HIMSS 2010 description that we've included for you.

And HIMSS isn't the only exciting event going on in Atlanta. From February 27 to March 1, the city will also play host for our 20 year reunion of Advanced Clinical Engineering Workshops. In coordination with WHO and PAHO, we are bringing together faculty and students from all over the world to meet and celebrate 20 years and 40 successful workshops together. In addition to the festivities, we will meet and talk about the future strategy for

(Continued on page 2)

Treasurer's Report

At the end of calendar year 2008, as the ACCE Board of Directors was working on the FY09 budget (ACCE's fiscal year goes from January 1st to December 31st), there were clear signs that the financial crisis that started in the United States was spreading rapidly around the world. Healthcare organizations everywhere were cutting expenses and looking for cost avoidance opportunities that could help their struggling bottom lines. Clinical Engineering departments were not going to be spared the pain of reduced budgets and more stringent approval processes for everything that was not considered essential to patient care. The following twelve months were going to be very challenging for a small international not-for-profit organization whose financial sustainability depends heavily on its members' desire and ability to further their professional development with education and networking. But even when faced with those grim economic conditions, the ACCE Board decided to approve an optimistic budget that would keep the organization solvent and on solid financial ground. The challenge was large but so was the determination and ingenuity of its members.

It is my honor and pleasure to present the results achieved by the hard work of many colleagues that believed in supporting and advancing the Clinical Engineering profession with their generous contributions of time and talent. Total 2009 income was $77,926 and represented only 91.0% of the budgeted $85,610. The 2009 income was even lower than the 2008 income by 7.4%. So "having to do more with less" was not just a management cliché but a concrete reality for the ACCE. With creative arrangements, kind contributions from medical instrumentation organizations, and careful monitoring of expenditures, ACCE was able to complete most of its planned projects below budget. The 2009 total expenses of $69.695 were 7.2% below the budgeted $75,112. Furthermore, the 2009 expenses were an impressive 15% lower than the 2008 expenses. Hard work and attention to details paid dividends.

So our organization has been able to deliver a modest but nevertheless significant net income of $8,957 against an optimistic budget of $11,500 in 2009. And this was done at a time when many larger and much more powerful business organizations have been bleeding red and even going out of business. Again, a remarkable achievement for a relatively small organization with one of the lowest membership fees in any professional field.

I take this opportunity to give many thanks to everyone who worked and contributed to make 2009 a successful year for ACCE. During these difficult times it is important for all the membership to feel confident that the Board of Directors values their support and takes its stewardship responsibilities very seriously.

Have a healthy and prosperous 2010.

Julio Huerta,

ACCE Treasurer

JHuerta@unch.unc.edu

President's Message (*Continued from page 1*)

international clinical engineering education and how ACCE will continue to play a role in helping other nations advance their national technology management programs.

Looking beyond HIMSS, we already have a full calendar. From Mar 21-23 in Washington, DC, there will be the First AMA-IEEE Conference on Medical Technology (http://ama-ieee.embs.org/) devoted to Individualized Healthcare, in which ACCE is a technical co-sponsor. The program doesn't have pure clinical engineering track, but the innovations that will be discussed there all require the same management principles that we use every day in healthcare.

The AAMI conference (www.aami.org/ac/index.html) will arrive before we know it and ACCE will be producing another successful ½-day symposium on June 26. We are excited for the conference also because we will be combining our booth space with IHE PCD to bring you a mini interoperability showcase. These details are still forming, but it should be an exciting conference!

Later in the year, from Sept 28-29, ACCE will be co-sponsoring the 2nd Medical Device Connectivity Conference in San Diego, CA. Stay tuned for more details on this event as it evolves but it will surely be just as informative as the 1st conference, which also proved to be a great venue for clinical engineering advocacy.

I'm looking forward to keeping you informed as these and many other activities get finalized for 2010. I encourage you to renew your membership and stay tuned to our newsletters and email announcements as these events unfold.

2010 Is a Great Year to Be a Clinical Engineer!

Cheers,

ACCE Healthcare Technology Foundation News

Strategic Plan

We continue to work diligently on our strategic plan. The executive board has had a series of lengthy meetings challenging ourselves on how to take the Foundation to the next level. We have been fortunate to work closely with board member Mike Dashefsky, VP of the Enterprise Business Unit at Nihon Kohden. He has brought a unique perspective as a new board member and industry representative. He has challenged us all to step back, appreciate where we came from yet develop a clearer understanding on what direction to progress. We focused on our mission statement and assessed the input from all board members. We are in discussions on our name, what it means, and does it fit our intended mission. We evaluated our current and desired future audience and how to achieve that within our mission. We spent considerable time reviewing our relationship to ACCE and the role ACCE can play within the future mission accomplishments. We began the establishment of an implementation strategy that focuses on core areas. It is important to be careful not to spread the resources too thin as that has proved to be problematic historically. How do we achieve the volunteers necessary to tackle the projects and provide deliverables? How do we obtain the fundraising required to ensure project success? How can we establish better name recognition? What collaborations should be fostered? What associations and other professional organizations would benefit? As you can see it has been a very reflective though arduous process. We have come a long way since our first meeting in October 2002. Our ultimate goal is to have a better understanding of the future direction of the ACCE Healthcare Technology Foundation.

2010 AAMI Foundation / ACCE Robert L. Morris Humanitarian Award

It is that time of year to start thinking of those folks who embody the Robert Morris gift. The deadline for nominations is March 15, 2010. Tobey Clark is addressing nominations internally with the foundation. Please feel free to contact him should you have any fantastic suggestions (Tobey.Clark@ITS.UVM.EDU). Following are relevant links:

www.aami.org/awards/morris.html

www.aami.org/awards/award.form.pdf

Look at the fabulous recipients we have had since inception! They ought to provide some inspiration.

Donations

Want to get a jump on your charitable contributions for 2010? Don't forget you can always donate to us!

Jennifer C. Ott, MSBME, CCE

Secretary, ACCE Healthcare Technology Foundation

secretary@accefoundation.org

William Hyman, ScD, PE

President, ACCE Healthcare Technology Foundation

president@accefoundation.org

AAMI Foundation / ACCE Robert L. Morris Humanitarian Award Winners

2009	J. Tobey Clark, CCE	**2004**	Alfred Jakniunas
2008	Yadin David, EdD, CCE, PE, HCSP	**2004**	Alfred Jakniunas
2007	Louis W. Schonder, CBET	**2003**	George I. Johnston, CCE
2006	Robert Pagett	**2002**	Herman R. Weed, PE
2005	David Harrington	**2001**	Robert Morris, CCE PE

ACCE Healthcare Technology Foundation

ACCE Healthcare Technology Foundation (AHTF)
5200 Butler Pike
Plymouth Meeting PA 19462
(610) 825-6067
http://www.accefoundation.org
AHTF is an independent, not-for-profit foundation

If you're looking for a chance to form a wide network of clinical engineers as well as the chance to earn a little extra cash, the AHTF is looking for you! The AHTF secretariat position is open and involves administrative work for the AHTF and the AHTF Certification Commission. If interested, please contact Caroline Campbell at Caroline.Campbell@trimedx.com

Perspectives from ECRI Institute:

Steris System1 and FDA

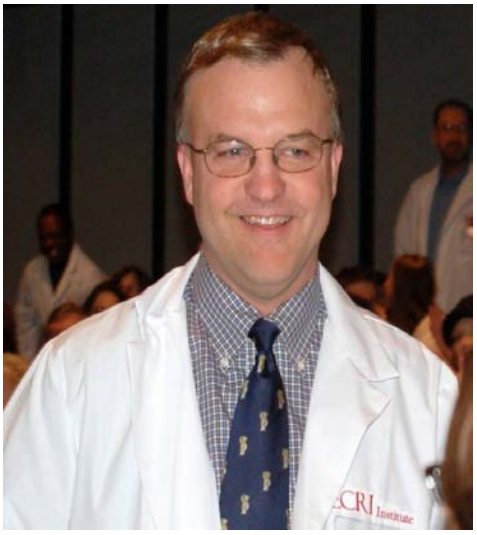
ECRI Institute has been keeping very busy over the last month or so fielding calls and other inquires from hospitals and many others related to the U.S. Food and Drug Administration (FDA) and the Steris System 1 (SS1) Sterile Processing System. For the few of you that are not familiar with this issue, on December 3, 2009, FDA notified healthcare facility administrators and infection control healthcare professionals about the regulatory status of the SS1 used in surgical and endoscopy suites for reprocessing (sterilizing or disinfecting) medical devices. FDA, stating that it has not assessed the ability of the system to safely disinfect or sterilize medical devices, recommended that users transition to alternative reprocessing methods as soon as possible to ensure continued patient safety. Basically, over a series of years, Steris failed to submit changes to its product for FDA clearance. FDA stated that the Steris changes may have impacted its product's safety and effectiveness. As a result, from FDA's perspective, the SS1 is an illegally marketed device with unproven safety or performance.

This is a big deal. As many as 20,000 SS1 Sterile Processing Systems are in use in the United States. ECRI Institute estimates that the total cost to replace all of these products may exceed $500 million. FDA has pointed out that it is "not aware of any confirmed cases of infection directly attributable to inadequate reprocessing by the SS1. So if there are no confirmed infection (i.e., safety problems), do hospitals and other healthcare facilities really need to comply with FDA's recommendation? Unfortunately, despite the extremely high cost, ECRI Institute believes that that they do because there remains the possibility that FDA could take stronger regulatory action in the future if it believes that potential risks remain unaddressed. Should such action impact the availability of parts, consumables (including the sterilant), or service, facilities still dependent on the SS1 could find themselves unable to meet reprocessing demand—and, therefore, at least some clinical needs—for some period of time. Additionally, given the high level of public attention FDA's notice has received—including extensive coverage in the lay media—hospitals continuing to use the SS1 may be subject to greater scrutiny (and perhaps increased liability) following suspected infection or injury of patients who may have been treated with devices reprocessed in the system, regardless of the actual source of the injury or infection.

Clearly this is a tough situation for hospitals and other healthcare facilities to be in. Many are saying that hospitals are literally stuck in the middle between a dispute between FDA and Steris. To help hospitals better prepare for their transition from the SS1, ECRI Institute has produced a series of Web-based resources that include its perspectives on this topic, reprocessor purchasing guidance, summaries of Steris-related alerts, and product comparison tables for reprocessor alternatives. Much of this information is available for free from ECRI Institute's public Web site. The link for the free information can be found at https://www.ecri.org/Forms/Pages/STERIS-System-1-(SS1)-Replacement.aspx.

Additional information is available at a Steris System 1 Resource Center on the member Web pages for ECRI Institute's Health Devices System, Health Devices Gold, and SELECTPlus services. The Resource Center includes a new discussion forum where ECRI Institute members can share their perspectives and comments on this topic with ECRI Institute staff.

Feel free to contact me at (610) 825-6000, ext. 5279 or jkeller@ecri.org if you would like to discuss this issue or if you would like information on how to access any of our online resources on this topic.



Jim Keller is ECRI Institute's Vice President for Health Technology Evaluation and Safety and a past Member at Large for ACCE's Board.

ACCE Clinical Engineering Certification Study Guide

The American College of Clinical Engineering has prepared a Study Guide for the Clinical Engineering Certification examination offered by the Healthcare Technology Certification Commission established under the ACCE Healthcare Technology Foundation. The Study Guide is available through ACCE for $30. To order a copy of the Guide, please make out a check payable to ACCE and send to:

Alan Levenson, ACCE Secretariat
5200 Butler Pike
Plymouth Meeting, PA 19462

Or e-mail Secretariat@ACCEnet.org and include credit card information (name on card, type of card, card number, and expiration date). *The ACCE Study Guide was written by an independent group of clinical engineers not associated with the exam process*

The View from the Penalty Box:

It does not seem possible that it has been more than 10 years since all of our technology was supposed to malfunction on that dreaded night of December 31, 1999. If we had listened to the "experts" the technology that we managed was going to fail and everyone would be in danger. Well we managed our technology and no one was put in danger and life went on and we went back into our caves to await the next crisis. I went looking for articles on how well we handled the problems and found very few that even mentioned a clinical engineer. Well, very belatedly here is a thank you for doing such a good job.

It has been said many times that if you stay around long enough you get to see the same thought process come back into vogue. It seems that there is a new interest in comparative analysis, as is was called in the 60's now gaining strength as bench marking. But as happened in the 60's, the aim is off as key costs are not being considered. At some point we, as a profession, are going to have to address and determine that cost of ownership of a device and from that determine the cost of a procedure. This is something that will be forced onto healthcare technology if the "bean counters" get the ear of our law makers who at some time may really want to get healthcare costs under control. I was recently told that a simple CT actually costs less than $6.00 per image while a chest X-Ray costs close to $75.00 per image. While I cannot verify these costs they did come from a reasonable source. Just for chuckles I checked some recent bills that I have on what the insurance companies paid for procedures and it looks like they paid $38.00 for the $75.00 chest X-Ray and $473.38 for the $60.00, (10 images), CT. Can you imagine what other true costs are relating to the prices charged and payments received? In the clinical lab the charges are even more unrealistic to the actual costs. Let's not even consider surgery.

What I am trying to say is that benchmarking is fine, but more needs to be included into the numbers, like cost of ownership, up-time, space and energy needs, personnel costs, supplies; and these numbers need to be shared. If hospital A is doing something for $100.00 per procedure and hospital B is doing the same thing for $175.00, then something is wrong somewhere and there needs to be a review of both sets of numbers to be sure that they are looking at the same things in the same way. Also what is good in Dallas might not be as good as or better than what is done in Chicago, so look closely at how the results were determined not just the numbers.

Sticking with my reputation of being a pain in the ***, I have contacted my local state legislators about a bill that was filed that would prevent car manufacturers from not providing their diagnostic software, at a reasonable cost, to all car repair personnel. I have asked them to include medical equipment into that legislation. The people that filed the bill are very upset that the local mechanic, charging $60 per hour cannot fix their car and they have to go to the dealer and get charged $90 per hour. What would these car owners think about what we have to pay to get the company just to show up to look at our equipment, in some cases $1,500 plus mileage just to walk into the hospital then $500 plus an hour to "fix" the problem with repairs parts at many times their actual costs. The car people are getting a good deal compared to us.

The pending healthcare legislation could be a great opportunity for our profession as costs are finally going to be looked at. Most of what hospitals charge today is based off of the DRG system which was developed from hospital charges of a few hospitals in and near New Haven CT, in the 70's. As a side note, with a separation of a few years, 2 students at Yale School of Management presented outlines on companies or systems, one was panned by the reviewers as never being able to work, that turned out to be FedEx, and the other, which received rave reviews on containing healthcare costs, was DRG's.

Now if we can present good numbers with the present technology to the right people we can impact healthcare costs. Some of the things that we will have to do are to become very strong on replacing obsolete technology, out of support items and old ideas that no longer work with better technology and practices. Another item to consider is to clean out your store rooms and shelves of items no longer used or supported giving the appearance that yours is a modern lab not an antique shop.

In closing we need communication between all of us to grow our profession. So talk about what needs to be done, write about what you have done and are doing, and let the world know that we are active, committed, and not all weird.

Dave Harrington

dave@sbttech.com

ACCE @ HIMSS 2010

Be sure to stop by our booth: CS01

Event	Date / Time	Location
Clinical Engineering and IT Symposium: Collaboration in a Time of Change	Sunday, Feb 28 9 AM - 5 PM	Georgia World Congress Center Room B208 *Separate HIMSS ticket required*
ACEW 20th Anniversary Reunion Dinner	Sunday, Feb 28 7PM – 11PM	The Trolley Barn 963 Edgewood Avenue, NE Atlanta, GA $40 for dinner *no HIMSS registration required*
ACCE Awards Ceremony & Meeting (held in conjunction with CEIT Collaboration reception)	Monday, Mar 1 6 PM – 9 PM	Hotel near Georgia World Congress Center, Location TBA *no HIMSS registration required*
IHE PCD Interoperability Showcase Tours	Tuesday, Mar 2 10 AM-1 PM 2:30 PM-5:30 PM	Georgia World Congress Center, Interoperability Showcase *HIMSS Conference registration required*
HIMSS Awards Banquet (ACCE presents CEIT Synergy Award)	Tuesday, Mar 2 6:30 PM – 9 PM	Omni Hotel at CNN Center Grand Ballroom *Separate HIMSS ticket required*
ACCE & HIMSS Breakfast	Wednesday, Mar 3 7 AM – 8 AM	Georgia World Congress Center, room TBD *HIMSS Conference registration required*
IHE PCD Interoperability Showcase Tours	Wednesday, March 3 10 AM-1 PM 2:30 PM-5:30 PM	Georgia World Congress Center, Interoperability Showcase *HIMSS Conference registration required*
ACCE sponsored Education Session: "Unique Healthcare Technology Solutions Used in Global Health" Mario Castenada & Antonio Hernandez	Thursday, Mar 4 10 AM – 11 AM	Georgia World Congress Center, room B302 *HIMSS Conference registration required*

International Report

Chinese Hospital CEO Meeting Focuses on Quality Management

Approximately 600 Chief Executive Officers from hospitals throughout China attended the 3rd National CEO conference held in Shanghai on November 5-7, 2009. The keynote speaker was Yuanli Liu, PhD, from Harvard School of Public Health, who is an expert on health system performance and reform. A theme associated with the conference was Hospital Quality Management. I presented in this track on medical device quality issues, and the benefits of management based on the U.S. experience. Dr. Sunny Sun from the National Institute of Hospital Administration, the agency that sets requirements for non-military government hospitals in China, discussed the development of first time hospital standards for medical equipment quality assurance (QA) and management. Currently, administering and performing quality assurance inspections in hospitals are the responsibility of the National Institute for Metrology. It is hoped that the rapidly evolving Clinical Engineering profession in China will have a primary role in medical equipment management and QA under the new guidelines.

Dr. Sunny Sun addressing the particiapnts

Tobey Clark,
ACCE ACEW Program Co-Leader
Tobey.Clark@ITS.UVM.EDU

CE Community Responds to Haiti Disaster

As soon as the news flashed about the epic-size disaster hitting Haiti Dr. Yadin David like many other clinical engineers and BMETs thought: "What can I do to help?" Living in Houston and experiencing the devastation of Katrina and Ike Hurricanes he knew that the need for and support of basic medical technology and utilities is immediate. The result was placing a call for clinical engineering professionals to come together and offer their expertise. Several social networks and healthcare voluntary groups such as Lou Schonder, Founder and Director of Earth-Med.org and Wayne Morse offered help in dissemination of the call for help. After consultation with the World Health Organization and the Pan American Health Organization (PAHO) it was decided that the best route to benefit from the response to the call for clinical engineering action was through Antonio Hernandez with PAHO. Indeed, the response was overwhelming. Within 72 hours, over 75

individuals offered to help. Most, volunteered their expertise and time. Expertise ranges from basic biomed knowledge to X-ray and imaging. Others offered expertise in medicine and orthopedics and yet others, being students, just offered their time and willingness to do whatever will be needed. There were also executives from companies that offered their products, like parts and accessories, training, and even CMMS to manage equipment inventory. More volunteers continue to register as this article is being printed. Yadin David said that being part of the healthcare community makes clinical engineering professionals one of the most caring group he knows. The response is so large and immediate that you feel good being the vehicle for delivering assistance. PAHO will use the collected database for their plans to conduct needs assessment and the recovery phase. Thanks to all who join the Clinical Engineering Community Relief effort. The people of Haiti need and thank you.

For more information on this effort and how you can help, please contact Yadin David at David@BiomedEng.com

Daughter of ACCE Member Home Safe from Haiti

Jessica Frick, 21, daughter of ACCE colleague Robyn Frick, has finally returned safe and sound to Maine from the recent devastation in Haiti with many stories to tell. Frick was greeted at about 6:30 PM on January 16th at the Bangor International Airport by her parents and two younger siblings.

ACCE member Robyn Frick(right) greeting his daughter Jessica at the airport Photo courtesy of Sarah Frick

"I felt like I couldn't breathe!" Said the mother, Cindy Frick, through tears of joy. "I'm just going to sit and look at her for a while."

Both Frick and her roommate, Yanica Faustin, 21, were evacuated out of Haiti on a military plane and arrived in Florida on Friday/Saturday at about 1:30 AM. Frick had contacted her family in the middle of the night and was gladly received. "We were all suddenly wide awake when we got the call and ready to hear her voice and for her to come home." Cindy said.

Frick and Faustin then took commercial flights from Florida to reach New York, where Frick safely left Faustin at her home in Brooklyn. Frick was also able to meet her boyfriend, Kirk Silver, 21, resident of New Jersey, who met her at the JFK airport and brought food and kept her company until her next flight to Bangor.

Frick confirmed that she was in a car when the quake hit. She felt the vibrations, thinking they were potholes in the road, then saw a building collapse, and thought it was just being demolished. She didn't realize what was happening until seconds later when she, Faustin, and Faustin's brother ran.

"We were just huddled down, we didn't know were to run. People were screaming, crying, and praying. It was mass chaos." Frick says about what happened during the earthquake. "We were covered in dust after it stopped. It was really scary."

After the quake, Frick spent the next few days outside due to the aftershocks that came at first fifteen minute intervals, then half-hour intervals, then occurring few and far between. They had little food and drink and little to no resources for bathing. The women were encouraged to stay with the children and do the cooking while the men went to help the survivors.

Frick's nightmare didn't end after the earthquake ended, however, as she, Faustin, and Faustin's father were mugged the next day on the street.

"We were walking over the rubble, and a big guy came up and said 'Camera! Camera!' in Creole [the national language of Haiti]." Frick states. "He threatened us with a cinder block, then grabbed my camera from my pocket by the exposed string. I said, 'Hey!' But Yanica's father told me to let it go." Faustin's necklace was also ripped off her neck. This shows how soon the looting started in the impoverished nation.

Frick is "so glad to be back." She finds the cold weather welcoming as well as basic needs such as food, water, and a shower. "I definitely won't forget, and I hope no one forgets about the people that aren't lucky enough to come home from Haiti like I am."

Submitted By Robyn Frick's family.

frickrw@aol.com

ACCE Hire a CE Project

HIMSS Annual Meeting 2010
Atlanta, Georgia

ACCE advocacy committee members, Valerie Yoder and Alyson Phillips, assisted by Tom Judd, Paul Sherman and Jon Blasingame are manning the ACCE booth and circulating during the annual HIMSS meeting in Atlanta, Georgia this year promoting the clinical engineering by targeting CIOs.

The team has assembled a packet of information describing skills clinical engineers would bring to a CIO's organization. We have created job descriptions, reference lists where clinical engineers are currently employed in IT organizations, and other material about ACCE and clinical engineers place in Healthcare.

The goal is to reach 100 CIOs and advocate for ACCE and clinical engineering.

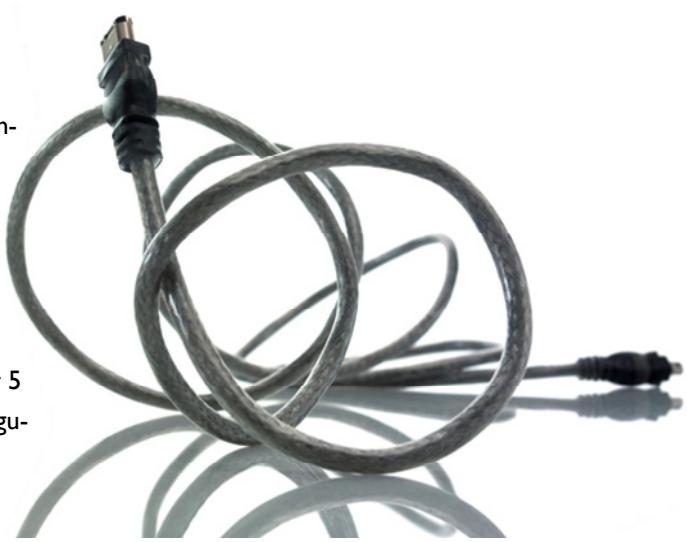
By helping to create more job opportunities for our profession and promoting ACCE, we hope to grow the organization.

Wish us luck!

Invitation to Demonstrations of Interoperable Medical Device Data Communication at HIMSS10

Electronic communication of data directly from medical device systems can significantly improve patient care and safety. With standards-based interoperable communication, institutions can select the "best of breed" for specific applications, mixing vendors and models, with assurance of compatibility. However, in the absence of interoperable communications this becomes a difficult and expensive undertaking, with additional overhead and maintenance requirements.

The Patient Care Device Domain (PCD) of Integrating the Healthcare Enterprise is concerned with integration use cases in which at least one actor is a regulated patient-centric point-of-care medical device. The PCD coordinates with other IHE clinical specialty based domains such as medical imaging and lab to ensure consistency of medical device integration solutions across all IHE technical frameworks, as well as the I.T. Infrastructure (ITI) domain to leverage common technical solutions that are deployed across the enterprise. In existence a scant 5 years, the PCD has developed messaging for:



- Device Enterprise Communication (physiologic and device operational data) from devices to CIS and EMR systems

- Point-of-care Infusion Verification (support for 5 rights-based pump configuration)

- Implantable Device – Cardiac – Observation (pacemaker data from home and clinic conveyed to medical record systems)

- Alarm Communication Management (limited in scope, it will become significantly more powerful this year)

- Rosetta Terminology Mapping (provides standards-based common terms, units of measure, other elements for patient and device data)

We invite you to spend a short time at the Interoperability Showcase at HIMSS10, Booth # 233, where you will see demonstrations of interoperable systems, and find help in meeting the demanding requirements of customers and regulators. Look for the Patient Care Device demonstrations where simulated clinical settings demonstrate:

- Continuity of care and documentation from home to hospital to physician and various follow up sites,

- Home health and pacemaker follow up leading to hospitalization

- Involvement of patient and family

- Improved workflow and clinical efficiency,

- Medical data immediately available when and where needed

- Alarm and alert communications

- Improvements in patient safety,

- Infusion pump medication management (5 rights)

- Descriptions of existing and future PCD technical profiles that support the ARRA / HITECH legislation and the requirements identified in the ONC Common Device Connectivity use case"

- Reduced development, implementation, acquisition, and installation costs and improved maintainability of the healthcare IT network and of medical devices and systems.

The PCD section of the Showcase will provide users, developers and vendors with important information. The PCD invites you to come, learn, discuss, and join in making the changes which benefit patients, staff, and the organization. More information is available from pcd@accenet.org.

Emmanuel Furst

efurst@imp-tech.com

Journal of Clinical Engineering – Call for Papers

The Journal of Clinical Engineering, which prints the ACCE News in each issue, is interested in papers from you. If you have an urge to write, and good clinical engineering activities or thoughts to share, please consider JCE as one of your outlets. One type of article not seen in a while is the Department Overview which presents how your department is structured and how it performs its functions. Shorter "Perspective" pieces are also welcome. You can discuss manuscript ideas with fellow member William Hyman, who is one of the editors of JCE. He can be reached at w-hyman@tamu.edu. Completed manuscripts can be sent to William or Michael Leven-Epstein at lecomm1@aol.com.

Medical Device Quality System Regulation Educational Forum

Risk Management through the Product Life Cycle

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Region (SWR), Dallas District Office (DALDO), in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled "Medical Device Quality System Regulation Educational Forum on Risk Management through the Product Life Cycle." This public workshop is intended to provide information about FDA's Medical Device Quality Systems Regulation (QSR) to the regulated industry, particularly small businesses.

Date and Time: The public workshop will be held on April 2, 2010, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the new Cowboy Stadium in Arlington, Texas. Directions to the facility are available at the FMDIC Web site at http://www.fmdic.org/.

Contact Person: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, Suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, e-mail david.arvelo@fda.hhs.gov.

Registration: FMDIC has a $250 early registration fee. Discounts for full-time students and government employees with valid identification are available. Early registration ends March 19, 2010. Registration is $300 thereafter. For more information on fees and/or to register online, please visit http://www.fmdic.org/. Registration on site will be accepted on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is $300 payable to the FMDIC. The registration fee will be used to offset expenses of hosting the event, including food, venue, and equipment.

If you need special accommodations due to a disability, please contact David Arvelo (see Contact Person above) at least 21 days in advance.

Transcripts: Transcripts of this event will not be available due to the format of this workshop. Digital event handouts will be posted online at http://www.fmdic.org/ or may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Room 12A-16, Rockville, MD 20857, after the public workshop at a cost of 10 cents per page.

Supplementary Information: The workshop is being held in response to the interest in the topics discussed from small medical device manufacturers in the Dallas District area. This workshop helps achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as an outreach activity by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the Medical Device QSR. The following topics will be discussed at the workshop: (1) standards and guidance, (2) risk management in design, (3) risk management in execution, and (4) risk management and post market surveillance.

Steve Juett,
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Note to ACCE Members from Al Levenson, Secretariat:

Well, here it is, a New Year and once again time for membership renewal. And once again, ACCE has not raised its annual dues; $60 for Individual, Associate and Fellow Members, and $30 for Candidate Members. A reminder: if you are a Candidate Member with the requisite three years of experience, you are now eligible for full membership. Or if you are contemplating changing your status, you will find the appropriate forms under the MEMBERSHIP tab on the home page.

How to renew? Right on line. Go to our website www.accenet.org and click on the yellow 'splash' on the upper right corner (aptly entitled "Membership Renewal"). You will be taken to the logon screen. If you have forgotten or misplaced your logon and password, please drop me a line and I will send it to you.

Finally, please take the opportunity to update your personal records in the Members Directory, especially contact information. And, as always, if you have any questions, comments or suggestions, again, please drop me a line.

Best regards and Happy New Year!

Alan Levenson, ACCE Secretariat

secretariat@accenet.org

Ray Zambuto Elected as AIMBE fellow

Ray Zambuto, President of Linc Health- was elected into the College of Fellows American Institute for Medical and Biological Engineering's (AIMBE). He will be inducted at a ceremony that will be held in Washington, DC, in February 2010. Recipients of this honor, considered one of the highest in the biomedical engineering discipline, are chosen for exceptional leadership and achievements in medical and biological engineering. The Fellows of AIMBE are elected based on their contributions that have had a major impact in biomedical devices and processes, treatment of diseases, and public policy related to all aspects of bioengineering.

Mr. Zambuto's induction as an AIMBE Fellow comes in recognition of his service as one of the clinical engineering industry's leaders for over 35 years. He has pioneered the evolving roles of clinical engineers as they have had to manage increasingly complex and converging medical and information technologies. As a highly respected member of both the medical and information technology communities, he has fostered collaboration that directly led to the formation of joint initiatives to insure the effective and safe interoperability of these diverse technologies.

Located in Washington, DC, AIMBE is the leading advocacy group for medical and biological engineering and is comprised of some of the most important leaders in science and engineering. Founded in 1991, AIMBE has earned a reputation as a prestigious public policy leader on issues impacting the medical and biological community. AIMBE is regarded by key legislators as the preeminent voice on the subject.

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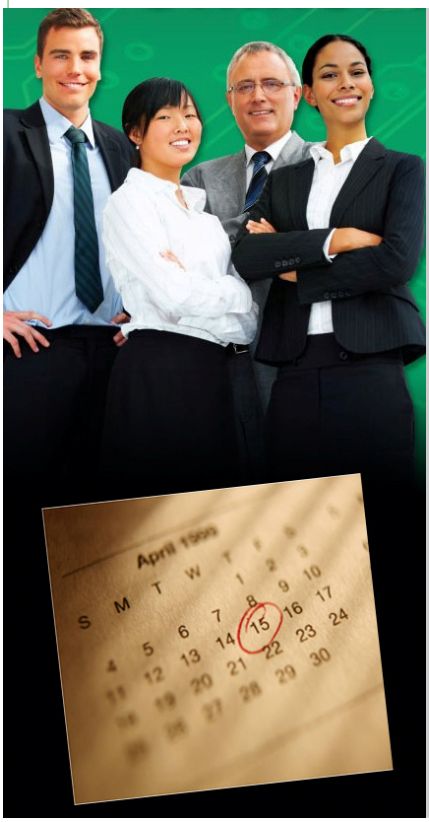

Calendar of Events

March 1-4, 2010

HIMSS Conference

March 11-13, 2010

AIIC (Italian Association of Clinical Engineering) 10th National Congress

Rome, Italy

http://www.aiic.it/on-multi/Home/articolo14008896.html

February 18, 2010

The Joint Commission Update

George Mills

March 18, 2010

How to Manage a Successful Imaging services Group

Grant Smith

April 15, 2010

Standards and Standards efforts in the Medical Device-Information System Interface

Bridget Moorman

May 27-30, 2010

Medicon 2010

Chalkidiki, Greece

www.medicon2010.org

June 26-28, 2010

AAMI conference

Tampa, FL

= ACCE Teleconference